



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S) : Lu, et al.
SERIAL NO. : 09/961,028
FILED : September 21, 2001
FOR : Artificial Lipoprotein Carrier System for Pharmaceutical Use.

GROUP ART UNIT : 1653
Examiner : A. Mohamed

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**Election of Invention in Response
to Restriction Requirement**

In response to the Examiner's correspondence dated December 31, 2003, pursuant to the Examiner's restriction requirement in the above-referenced patent application, Applicants provisionally elect with traverse to prosecute the invention of group I, namely claims 1-17 and 33, which are drawn to a pharmaceutical composition comprising a microemulsion with a lipid core and amphaphatic lipid layer, classified in class 424, 514 and 530, subclasses 130.1, 450, 7 and 359, respectively. In addition, in order to comply with the Examiner's requirement for a species election, Applicants provisionally elect with traverse to prosecute the species where the phospholipid is phosphatidylcholine, the bioactive agent is DNA, the lipidized protein is N-palmitoyl polylysine and the triglyceride is triolein. It is respectfully submitted that the elected species provides a sufficiently narrow group of embodiments to allow the efficient prosecution of the instant application. Claims 1, 3-4, 7-8, and 12-15 are readable thereon.

Nonwithstanding the species election, Applicants respectfully traverses the Examiner's requirement for restriction. Applicant respectfully requests the Examiner reconsider his restriction requirement. Applicant respectfully submits that prosecution of all of the originally filed claims should not be restricted to the elected invention, for the reasons which are set forth hereinbelow.

According to M.P.E.P. §803, restriction by the Examiner of patentably distinct inventions is proper if the claimed inventions are independent and a *serious burden* would be placed on the Examiner if restriction was not required. Applicant respectfully submits that the presentation of the originally filed claims would not place such a serious burden on the Examiner as to require restriction. All of the originally filed claims are related, though patentably distinct chemical compositions, methods of increasing the half-life of a drug and methods for ameliorating a pathological condition.

Although the claimed invention groups are generally patentably distinct from each other, Applicant respectfully submits that any search the Examiner would need to conduct in examining the instant application would not be unduly burdensome. Moreover, the examination of all of the originally filed claims in the instant application would not place such a serious burden on the Examiner as to require restriction.

Applicants understand the general policy considerations for the Patent Office's requirement for restriction in certain instances. In this instance, however, those considerations do not weigh in favor of restricting the inventions here. In determining the appropriateness of restriction, one must also consider the countervailing consideration that, in each instance, Applicant wishes the Patent Office to examine his or her application with a certain degree of "administrative efficiency" and wishes to have patent claims issue which reflect the breadth of his or her invention.

Applicants respectfully submit that the originally filed claims are sufficiently narrow to allow the Examiner to determine patentability without being subjected to the serious burden referred to in M.P.E.P. §803. Consequently, Applicant respectfully requests that the Examiner withdraw the restriction requirement. Alternatively, Applicants respectfully request that the Examiner extend consideration to examining all of the claims of group I inasmuch as the

compositions are conceptually related and are all pharmaceutical compositions.

The Examiner is cordially requested to call the undersigned attorney if the Examiner believes that a telephonic discussion may materially advance the prosecution of the instant application in any way.

Respectfully submitted,

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By:

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Dated: March 23, 2004

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 23, 2004.

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